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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,788	04/25/2001	Per-Olof Larsson	PL9824	3855

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GE HEALTHCARE BIO-SCIENCES CORP.
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EXAMINER

VO, HAI

ART UNIT	PAPER NUMBER
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1771

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/763,788

Applicant(s)

LARSSON ET AL.

Examiner

Hai Vo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-12 and 17-32 is/are pending in the application.
- 4a) Of the above claim(s) 20-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-12,17-19,31 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>01/22/07</u> . | 6) <input type="checkbox"/> Other: _____ |

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1. Objections of claims 3 and 4 are considered moot in view of the cancellation of the claims.
2. The art rejections over WO 93/19115 in view of Lihme et al (US 5,866,006) are maintained.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 6-10, 12, 17-19, 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/19115 in view of Lihme et al (US 5,866,006).

In light of the specification (page 2, lines 18-21), the recitation "with exception of the case that the composite contains an electrically monolithic secondary component which is intended to be, or is connected between two electrodes" means that the composite containing an electrically monolithic secondary component which is connected between two electrodes is completely excluded from the claim. WO'115 teaches a porous polysaccharide gel useful in a high performance liquid chromatography (HPLC) having a net work of two continuous phases, an aqueous polysaccharide phase and an organic phase, wherein the aqueous polysaccharide phase includes small diameter pores which are interconnected to give flow passages through the gel, and the organic phase

is the superpore-forming phase comprising large diameter flow through pores (abstract, and page 4). The HPLC can be operated in both fluidized bed and packed bed. WO'115 discloses the polysaccharide comprising superpores in the range of 5 to 100 microns and micropores in the range of 30 to 500 Angstroms (page 3), meeting the specific ranges disclosed at page 1, lines 10-14 of Applicant's specification. WO'115 does not specially disclose the super-porous polysaccharide containing the gel phase with micropores outside the superpores. However, the pore arrangement would be inherently present since the WO'115 is using the same materials and the same mixing technique to prepare the porous material as Applicant. WO'115 discloses the polysaccharide gels in the form of discrete particles (examples 3, 5 and 7). WO'115 discloses the super-porous material being coupled with various ligands (examples 8, 9 and 12). WO'115 is silent as to the secondary component of the composite material. Lihme, however, discloses a conglomerate suitable as a matrix carrier in a fluidized bed chromatography comprising a blend of a basic particle, a conglomerating agent and an active substance (column 7, lines 25-55, and column 8, 64-67). Lihme's conglomerating corresponds to the WO' 115 super-porous polysaccharide. Lihme discloses that the conglomerating agent is agarose (column 21, lines 19-20). Lihme discloses that agarose is the active substance (column 22, line 5). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ basic particles in combination with the super-porous polysaccharide of WO'115 motivated by the desire to obtain a

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matrix carrier having a controlled relative density with respect to the fluid. The basic particles of Lihme is mixed with the super-porous material of WO'115 in accordance with the teachings of Lihme. This is what Applicants do to form a composite material; therefore, it is the examiner's position that the basic particles would be substantially inherently present in both the super-pores and in the gel phase. The same token is applied to the position of the basic particles which are outside the super-pores but inside the main component's gel phase.

Lihme discloses the ligand is coupled to the conglomerating agent (column 18, lines 47-50). Lihme teaches that the ligand keeps the basic particles together and provides mechanical stability (column 17, lines 25-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to introduce ligand into carrier matrix motivated by the desire to keep the basic particles together and provide mechanical stability.

With regard to claims 17-19, Lihme reads on the claim limitations (column 8, line 62 et seq.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the composite material of WO'115 as modified by Lihme for variety applications as set forth in the claims because such is a, desirable, excellent solid phase matrix for use in variety applications and Lihme provides details to practice the invention of WO'115.

5. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/19115 in view of Lihme et al (US 5,866,006) as applied to claim 1 above,

further in view of Torobin (US 5,212,143). Neither WO'115 nor Lihme discloses or suggests the pore size of the low density basic particle, namely the pore size of the hollow glass microsphere. Torobin, however, discloses the hollow glass microsphere for use in conjunction with genetically engineered bacteria or other living microorganisms, antibiotics or enzymes in processes to produce or separate and purify pharmaceutical or chemical products having a pore size of 1 to 3 microns (examples 3 and 7). WO'115 discloses the polysaccharide comprising superpores in the range of 5 to 100 microns and micropores in the range of 30 to 500 Angstroms (page 3). Likewise, it is clearly apparent that the secondary component having average pore diameter greater than the average pore diameter of the main component in the gel phase. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the hollow glass microsphere having an average pore size in the range as disclosed in the Torobin invention because such a pore size is known in the hollow microsphere art and Torobin provides necessary details to practice the invention of WO'115 and Lihme.

Response to Arguments

6. The art rejections over WO'115 and Lihme have been maintained for the following reasons. Applicants argue that Lihme teaches fluidized bed chromatography while WO'115 is concerned with packed bed chromatography. The examiner respectfully disagrees. WO'115 discloses a porous polysaccharide gel useful in a high performance liquid chromatography (HPLC)

which is known to be successfully operated in fluidized bed columns as evidenced by Goetz et al (US 5,055,194). Therefore, WO'115 broadly discloses the porous polysaccharide gel useful in fluidized bed chromatography as well.

Applicants contend that fluidized bed chromatography cannot be used in HPLC. The examiner directs Applicants' attention to the Goetz Patent which will be relied upon as the evidence to show that HPLC is successfully operated in a fluidized bed.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hai Vo whose telephone number is (571) 272-

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1485. The examiner can normally be reached on Monday through Thursday, from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on (571) 272-1478. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HV

Hai V.

**HAI VO
PRIMARY EXAMINER**